MAY 21 2002

# Appendix 3I 510(k) Summary

Information shown in this section is furnished in accordance with 21 CFR 807.92. The paragraph headings shown below correspond directly with those in 21 CFR 807.92. Paragraph titles are paraphrased or derived from the CFR text, and are included for reference only.

**807.92(a)(1) Name, address, telephone number, contact person, and preparation date:**

- **Submitter's name and address:**
  Osteometer MediTech, Inc.
  12515 Chadron Avenue
  Hawthorne, CA 90250

- **Submitter's telephone number:**
  **Phone:** (310) 978 3073
  **Fax:** (310) 676 0948
  **Email:** rkrishnamurti@osteometer.com

- **Contact Person:**
  Raja Krishnamurti, Ph.D.
  Quality Assurance and Regulatory Affairs Specialist
  Osteometer MediTech, Inc.
  12515 Chadron Avenue
  Hawthorne, CA 90250

- **Date this summary was prepared:**
  April 24, 2002

**807.92 (a)(2) Trade/Proprietary name, Common/Classification name:**

- **Trade/proprietary name of the device:**
  DexaCare® G4

- **Common name:**
  Bone Densitometer

- **Classification name:**
  Bone Densitometer

**807.92 (a)(3); Legally marketed device (predicate device) to which equivalence is claimed:**

- Osteometer MediTech DTX-200 Bone Densitometer, described in 510(k) K964562.

**807.92 (a)(4); Description of the device that is the subject of this premarket notification:**

The DexaCare® G4 is a cost effective, table top bone densitometer. The DexaCare® G4 is a modification of the predicate Osteometer MediTech DTX-200 device listed in 510(k) K964562.

The DexaCare® G4 candidate device is a dual energy system, where the measured object, in this case the forearm, by the software, is divided into two compartments, bone and soft-tissue. Having two energies, and two compartments (unknowns) it is possible to establish and solve two formulae with two unknowns.

The X-ray generator is driven at 55kV, with a current of 300μAmps. The beam is filtered with Tin (Sn), using the K-Edge of this material to enhance the separation of the low and the high energy. The average energy peaks are approximately 29 keV, and 46 keV respectively. A highly stable X-ray output, together with a source collimation of 1 mm and a pixel resolution of 0.4mm X 0.4mm, yields images of very high quality.

The detector is a sandwich construction, using solid state photodiodes consisting of two diodes with scintillation material. The two energies are separated by the sandwich construction. The X-ray beam meets the first scintillator, where predominantly the low energy is detected, and then it meets the second scintillator, where the rest of the energy is detected.

The typical time to estimate bone mineral content and bone mineral density is approximately four minutes. The effective patient dose is estimated to be 0.1 micro Sievert per scan.

**21 CFR 807.92 (a)(5); Intended use:**

The DexaCare® G4 device estimates bone mineral content (BMC, in grams) and bone mineral density (BMD, in grams/$cm^2$). This is the same intended use as the predicate device.

**21 CFR 807.92 (a)(6); Technological characteristics:**

The technological characteristics and diagnostic functions of the DexaCare® G4 device are unchanged from the predicate device. Key characteristics are listed below:

- **Fundamental Scientific Technology:** The DexaCare® G4 uses noninvasive dual X-ray photon absorptiometry (DXA) to estimate bone mineral content and bone mineral density.

- **Major System Components:** The device consists of a computer, keyboard, monitor, printer, and scanner system using an X-ray transmission source.

- **X-ray transmission source:** The device uses an X-ray generator driven at 55kV, with a current of 300μAmps.
- **Calibration**: The DexaCare® G4 uses a line-by-line calibration system to ensure good precision.
- **Imaging technique, data acquisition, and quality control phantom**: These characteristics are unchanged from the predicate device.
- **Source Collimation**: 1mm diameter.
- **Accuracy and precision error:** Accuracy and precision error of the DexaCare® G4 candidate device is comparable to the DTX-200 predicate device.

**510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on performance data shall also contain the following:**

**21 CFR 807.92(b)(1); Brief discussion of the nonclinical tests submitted, referenced, or relied on in this premarket notification submission:**

There were no nonclinical tests submitted, referenced, or relied on in this submission.

**807.92(b)(2); Brief discussion of the clinical tests submitted, referenced, or relied on in this premarket notification submission:**

A clinical validation study was conducted to compare the performance results of the DexaCare® G4 to results of the predicate DTX-200 device. The test was performed in-house at the facilities of Osteometer MediTech, Inc. in Hawthorne, CA.

The test consisted of 16 subjects, who were measured 5 times each on 3 systems, with repositioning of the forearm between each measurement.

Each subject was measured on two different DTX-200 systems and a DexaCare® G4 system to demonstrate the cross-correlation between the predicate equipment types and the new candidate device.

A paired *t*-test was used to assess whether BMC and BMD measurements on the different devices were signficantly different. Linear regression analysis was used to examine the correlation between devices.

A summary of the clinical validation study, and conclusions, appears in Appendix 3H of this submission.

**807.92(b)(3) Conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well or better than the predicate device:**

The correlation observed between the DexaCare® G4 and the DTX-200 was similar to that observed between the two DTX-200 devices. The differences observed in BMC and BMD between the DexaCare® G4 and DTX-200 were small and not clinically signficant.

The clinical performance of the DexaCare® G4 is similar to that of the DTX-200.

**...End of 510(k) summary...**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2002

Raja Krishnamurti, Ph.D.
Quality Assurance and
Regulatory Affairs Specialist
Osteometer MediTech, Inc.
12515 Chadron Avenue
HAWTHORNE CA 90250

Re: K021331
Trade/Device Name: DexaCare® G4 Bone Densitometer
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: II
Product Code: 90 KGI
Dated: April 24, 2002
Received: April 26, 2002

Dear Dr. Krishnamurti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# 5 Indications for Use Statement (FDA form)

Ver/ 3 - 4/24/96

Applicant: ***Osteometer MediTech, Inc.***

510(k) Number (if known): _____

Device Name: ***DexaCare® G4 bone densitometer***

Indications For Use:

***To estimate bone mineral content (BMC, grams) and bone mineral density (BMD, grams/cm$^2$).***

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K021331

*Prescription Use* √